DESIG. ...

CONCERNING A FILING UNDER 35 U.S.C. 371

09/11/7030

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/RU97/00026	02/10/97	02/14/96; 02/14/96; 04/26/96

TLE OF INVENTION: Medicament and Method

PLICANT(S) FOR DO/EO/US: O. EPSHTEIN

PTO/PCT Rec'd 12 AUG 1998

plicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
- ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
- ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
- ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date

- ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☒ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US)
- ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).

- ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.

- ☒ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

- ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).

- ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☐ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☐ Other items or information:

rch Report has been prepared by the EPO or JPO.....

rnational preliminary examination fee paid to USPTO (37 CFR 1.482) $640.00

international preliminary examination fee paid to USPTO (37 CFR 1.482) international search fee paid to USPTO (37 CFR 1.445(a)(2))... $710.00

ther international preliminary examination fee (37 CFR 1.482) nor rnational search fee (37CFR 1.445(a)(2)) paid to USPTO..... $950.00

rnational preliminary examination fee paid to USPTO (37 CFR 1.482) all claims satisfied provisions of PCT Article 33(2)-(4)..... $90.00

ENTER APPROPRIATE BASIC FEE AMOUNT			=	$
of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 om the earliest claimed priority date (37 CFR 1.492(e)).				$
ns	Number Filed	Number Extra	Rate	
Claims	-20 =		X $22.00	$
nt Claims	- 3 =		X$78.00	$
dependent claims(s) (if applicable)			+$250.00	$
TOTAL OF ABOVE CALCULATIONS			=	$
on by 1/2 for filing by small entity, if applicable. Verified Small Entity statement o be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$
SUBTOTAL			=	$
up fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 from the earliest claimed priority date (37 CFR 1.492(f)).			+	$
TOTAL NATIONAL FEE			=	$
ecording the enclosed assignment (37 CFR 1.21(h)). The assignment must be anied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	$
TOTAL FEES ENCLOSED			=	$
			Amount to be: refunded	$
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A check in the amount of $ 535 to cover the above fees is enclosed.

Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 26-0085 . A duplicate copy of this sheet is enclosed.

Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR) or (b)) must be filed and granted to restore the application to pending status.

END ALL CORRESPONDENCE TO:

I. ZBOROVSKY
6 Schoolhouse Way
Dix Hills, N.Y. 11746

Signature

I. ZBOROVSKY
Name

28,563
REGISTRATION Number

Applicant or Patentee: EPHSTEIN, Oleg Illiich
Serial or Patent No.:
Filed or Issued:
For: *MEDICAMENT AND METHOD OF TREATING AN ORGANISM WITH MEDICAMENTS*

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 cfr 1.9 (f) AND 1.27 (b) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled

MEDICAMENT AND METHOD OF TREATING AN ORGANISM WITH MEDICAMENT
PCT/RU96/00026

[X] the specification filed herewith
[ ] application serial no. _____, filed _____
[ ] patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9 (c).

Each person, concern or organization to which I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.

[ ] no such person, concern, or organization
[ ] persons, concerns or organizations listed below

*NOTE: Separate verified statements are required from named person, concern or organization having rights to the invention overring to their status as small entities. (37 CFR 1.27)

NAME: _____
ADDRESS: _____
[ ] individual [ ] small business concern [ ] nonprofit organization

NAME: _____
ADDRESS: _____
[ ] individual [ ] small business concern [ ] nonprofit organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitle to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information on belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Full name of sole or first inventor: EPHSTEIN, Oleg Iliich

First inventor's signature: O. Epshtein Date: 3 abg 1998

Residence & Post Office Address: 22 Yan Rainis Blvd, D. 22, korp. Z, kv. 230, Moscow 123373 Russia

Citizenship: Russian

Applicant or Patentee: EPHSTEIN, Oleg Illich
Serial or Patent No.:
Filed or Issued:
For: *MEDICAMENT AND METHOD OF TREATING AN ORGANISM WITH MEDICAMENTS*

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MEDICAMENT AND METHOD OF TREATING AN ORGANISM WITH MEDICAMENT

[X] the specification filed herewith
[ ] application serial no. _____, filed _____
[ ] patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9 (c).

Each person, concern or organization to which I have assigned, granted, conveyed or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below.

[ ] no such person, concern, or organization
[ ] persons, concerns or organizations listed below

*NOTE: Separate verified statements are required from named person, concern or organization having rights to the invention overring to their status as small entities. (37 CFR 1.27)

NAME: _____
ADDRESS: _____
[ ] individual [ ] small business concern [ ] nonprofit organization

NAME: _____
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[ ] individual [ ] small business concern [ ] nonprofit organization

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information on belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Full name of sole or first inventor: EPHSTEIN, Oleg Iliich

First inventor's signature: O. Ephstein Date: 3 Aug 1998

Residence & Post Office Address: 22 Yan Raiynis Blvd, D. 22, korp. Z, kv. 230, Moscow 123373 Russia

Citizenship: Russian

MEDICINAL PREPARATION AND A METHOD OF MEDICINAL ACTION ON HUMAN ORGANISM

Field

This invention relates to medicine, namely, to medicinal preparations for use in therapy combining the methods of homeopathic and conventional therapy.

Background of the invention.

Contemporary pharmacotherapy extensively uses medicinal preparations produced chemically or derived from natural raw materials (of botanical, mineral or animal origin). These preparations exhibit therapeutic value and therefore can be applied in a certain range of therapeutic doses.

Also known are homeopathic medicines which contain therapeutic substances in minute, potentiated doses obtained by multiple successive dilution and shaking of the initial medicinal substance or of its trituration.

The latter group can be extended to preparations containing an indifferent material carrier (hereinafter referred to as 'carrier') (water, saline solution, alcohol, etc.) with bioenergetically transferred information on a bioactive substance obtained by homeopathic method (i.e. information on a homeopathic preparation); the field that the carrier posesses has a certain frequency spectrum (references: Patent of Germany 2810344, CL. A61H 39/00, 1984; Patent of Russian Federation 2033784, CL. A61H 39/00, 1995; Patent of Russian Federation 2042349, CL. A61J 3/00, 1995).

The principal disadvantages of the conventional medicines both in therapeutic and homeopathic doses are: discriminatory curative effect dependent on individual sensitivity and psychophysical state of the patient, and possible adverse undesirable after-effects.

Also known is a method of medicinal action on human organism by medical preparation exposed to external physical factor - gamma-radiation - which enhances activity of the medicine (Patent of Russian Federation 2035167, CL. A61K 35/64, 1995). Yet this approach has limited therapeutic applicability.

Description of the invention.

An object of the present invention is to create: a fundamentally new class of medicinal preparation (medicinal form) for more effective therapeutical action of the administered medicine; a method of medicinal influence on human organism, free of undesirable adverse after-effects, allergic and/or toxic reactions.

In accomplishing the foregoing objects, there is provided a medicinal preparation of a carrier with information on bioactive substance; according to the present invention, the preparation should constitute an active medicinal substance in therapeutic dose with bioenergetically transferred information thereto from potentiated medicinal preparation; the latter is produced by means of homeopathic methods and has initial chemical formula (composition) identical with that of the active medicinal substance.

PREFERRED EMBODIMENT OF THE INVENTION.

The invention constitutes medicinal preparation comprising a carrier provided with information on a bioactive substance. According to the invention, the carrier comprises: (1) an active medicinal substance in therapeutic dose, (2) a potentiated medicinal preparation produced by methods of homeopathy and combined with (1) by admixing or incorporating thereto. The potentiated preparation has initial chemical formula

(composition) identical to that of the active medicinal substance in therapeutic dose.

It is preferred that the active medicinal substance in therapeutic dose and potentiated medicinal preparation admixed thereto had similar (identical) medicinal form.

Also, in accomplishing the stated objects it is provided, in accordance with the invention, that in medicinal action on the organism the medicinal substance in therapeutic dose and potentiated medicinal preparation produced by homeopathic methods are administered simultaneously. The latter preparation has initial chemical formula (composition) identical to that of the former one. In doing this, the medicinal substance in therapeutic dose and the potentiated medicinal preparation may be administered as a single medicine combined thereof at the moment of production, or as separate medicinal forms administered simultaneously, but in either cases as medicines prepared separately.

Conceptually, the present invention claims a novel category (class) of medicinal preparations and/or medicinal forms that can be specified as "Bipathic", combining therapeutic values of medicinal substance in therapeutic dose and potentiated homeopathic preparation chemically homogeneous (in original formula or composition) but different in mechanism of action on the organism. This combination promotes biological activation and induces positive morphological and functional changes in form of "systemic adaptation" responsible for increased therapeutic efficiency of the active medicinal substance with reduced risk of patients' individual reactions and undesirable adverse after-effects.

Moreover, "bipathic" simultaneous administration of medicinal substance in therapeutic dose and potentiated preparation, according to the invention: (1) provides lower conventional doses of the substance, (2) prevents habituation due to enzyme "induction", (3) prevents overdosage owing to neutralization of negative energies and stimulation of certain organs and of the whole organism.

PREFERRED VARIANT OF REALIZATION.

Medicinal action on the organism is effected by administration of the claimed "bipathic" medicinal preparation.

The medicinal preparation is produced, in accordance with the present invention, from medicinal substance (carrier) obtained chemically or derived from botanical, mineral or animal raw material with therapeutic properties; the preparation can be applied in any known dosage form (solid, liquid, soft, for injections) convenient for practical use in medicinal action on the organism.

EXAMPLE 1.

Prior to transfer of bioenergetic information, 10 ml of 0.5% solution of atropine sulphate (medicine in therapeutic dose) as a carrier, and as a bioactive substance, potentiated preparation Atropini Sulfati C30 obtained by multiple successive dilution and shaking in accordance with homeopathic method, are placed in two separate containers mounted on current-conducting plates connected via a circuit of a known recorder of information signal. During bioenergetic information exchange, information on homeopathically potentiated initial active substance - atropine - is transferred to the carrier. Potentiated atropine has chemical formula identical to that of the carrier and posseses field with

certain frequency spectrum. The obtained medicine is applied in ophthalmology as a mydriatic for diagnosis and treatment of inflammatory conditions; it is devoid of accomodation paralysis as an adverse effect.

EXAMPLE 2.

0.01 g of potentiated homeopathic preparation Acidum Salicylicum is pressed into a pill containing 0.5 g of acetylsalicylic acid. The former is produced in accordance with homeopathic method by saturating a neutral substance, lactose, with solution of Acidum Salicylicum in C30 potency. By potentiating, the initial substance - acetylsalicylic acid - is bioenergetically transformed in accordance with homeopathic method into an information form, and the latter is directly transferred by pressing on the carrier posessing chemical formula identical to that of the initial substance. The "bipathic" medicine obtained so demonstrates effective analgesic, anti-inflammatory and antipyretic action with no adverse or allergic reactions. Its therapeutic effect in influenza is accelerated and augmented.

EXAMPLE 3.

A total of 0.005 mg of potentiated prednisolone produced by homeopathic method in the 12th centile dilution (Cortex C12) is incorporated into a carrier - pill containing 1.0 ml of prednisolone - by impregnation with several capillaries. The obtained "bipathic" remedy influences actively carbohydrate and protein metabolism due to augmented anti-inflammatory, desensitizing and anti-allergic qualities of the initial therapeutic substance. When applied for endocrine disorders, it notably reduces severe metabolic disturbances, such as Cushing's syndrome. Positive results devoid of adverse complications can be obtained in cirrhotic liver.

EXAMPLE 4.

A total of 1.0 ml of potentiated Insulinum C30 produced by homeopathic method through multiple dilution and shaking is admixed to liquid carrier containing 1.0 ml (40 U) of insuline for injections. In the mixture, the hormone demonstrates augmented and prolonged specific action to regulate carbohydrate metabolism, to stimulate assimilation of glucose in the tissues and to promote cellular glucose intake. The obtained "bipathic" remedy is administered in injections for diabetes mellitus and provides therapeutic efficiency at lower doses and reduced risk of adverse effects.

EXAMPLE 5.

A total of 1.0 ml of potentiated remedy Zincum Metallicum produced by homeopathic method in soft form is incorporated into the carrier comprising 10 ml of zinc paste. The obtained "bipathic" remedy is applied in skin diseases. It demonstrates augmented antiseptic, disinfecting and astringent action devoid of skin irritation.

EXAMPLE 6.

In therapy of neoplasms, 20 mg of sarcolysine is injected in 10 ml of saline solution synchronously ("bipathically") with a few (10-15) drops of oral potentiated Sarcolysinum in centile dilution C200. This method of therapeutical action provides lower toxicity of the active medicine and increased therapeutic efficiency.

INDUSTRIAL APPLICABILITY.

To manufacture therapeutic preparation comprising a medicine in therapeutic dose as the carrier with bioenergetically transferred information on potentiated preparation produced by means of homeopathic methods and having initial chemical formula (composition) identical with that of the carrier, one can use known device for

recording and transfer of information signal (refer to foregoing Patents: Patent of Germany 2810344; Patent of Russian Federation 2033784; Patent of Russian Federation 2042349).

In doing so the potentiated preparation is (1) produced from the initial substance by multiple successive dilution and shaking or trituration thereof with lactose in accordance with known homeopathic method and in any conventional dosage form (for example, refer to [Гомеопатические лекарственные средства. Руководство по описанию и изготовлению. Доктор Вильмар Швабе «Руководство по изготовлению гомеопатических лекарств» 1950 г.. Пер с немецкого. Под редакцией В.И. Рыбака. Москва, 1967.]) and (2) incorporated into carrier - the medicinal substance in therapeutic dose. The incorporation is performed synchronously with manufacturing of the carrier, for example: by pressing the pellets of lactose impregnated with solution of potentiated substance into the pills of active medicinal substance; by impregnation of the pills of active medicinal substance with dilution of potentiated substance; by mixing the noted components in the same (liquid or soft) dosage form. These procedures are technically accessible even for industrial application in a pharmacy.

CLAIMS OF THE INVENTION.

What claimed is:

1. A medicinal preparation comprising material carrier with information on bioactive substance, is characterized in that the carrier presents an active medicinal substance in therapeutic dose, and information is transferred bioenergetically thereto from potentiated medicinal preparation produced by homeopathic methods; the said potentiated medicinal preparation has initial chemical formula (or composition) identical with that of the active medicinal substance.

2. A medicinal preparation comprising material carrier with information on bioactive substance, is characterized in that the carrier presents an active medicinal substance in therapeutic dose, and combined with the said substance is potentiated medicinal preparation which is produced by homeopathic methods and has initial chemical formula (or composition) identical with that of the said active substance.

3. A medicinal preparation according to claim 2, is characterized in that active medicinal substance and potentiated medicinal preparation combined therein have similar (identical) dosage form.

4. A method of medicinal action on the organism, wherein active medicinal substance in therapeutic dose and potentiated medicinal preparation produced by homeopathic methods are administered simultaneously, and the said potentiated preparation has initial chemical formula (or composition) identical with that of the active medicinal substance.

SUMMARY OF THE INVENTION.

A medicinal preparaton constitutes an active medicinal substance in therapeutic dose as a carrier with bioenergetically transferred information from potentiated medicinal preparation; the latter is produced by means of homeopathic methods and has initial chemical formula (composition) identical with that of the active medicinal substance.

In preferred embodiment of the invention, the medicinal preparation presents the carrier containing an active medicinal substance in therapeutic dose, and combined therewith (by incorporating, dissolving or admixing) is a potentiated medicinal preparation produced by the methods of homeopathy. The latter preparation has initial chemical formula (composition) identical to that of the active medicinal substance in therapeutic dose.

The active medicinal substance in therapeutic dose and the potentiated medicinal preparation have similar or different medicinal dosage forms.

The invention is accomplished either by: (1) administering the said medicinal preparation, or (2) active medicinal substance in therapeutic dose and potentiated medicinal preparation obtained by homeopathic methods, are produced separately and administered simultaneously, and the said potentiated preparation has initial chemical formula (or composition) identical with that of the active medicinal substance.

DECLARATION AND POWER OF ATTORNEY FOR NATIONAL STAGE OF PCT PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled *MEDICAMENT AND METHOD OF TREATING AN ORGANISM WITH MEDICAMENTS*, the specification of which was filed as PCT International Application number PCT/RU97/00020 on 10 Feb 97 and was amended under PCT Article 19 on _____ (if applicable).

I hereby state I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior foreign application(s)			Priority claimed	
96102195 (Number)	Russia (Country)	February 12, 1996	X Yes	____ No
96102209 (Number)	Russia (Country)	February 12, 1996	X Yes	____ No
96107564 (Number)	Russia (Country)	April 24, 1996	X Yes	____ No

As a named inventor, I hereby appoint the following attorney to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Ilya Zborovsky, Reg. No. 28 563

Direct all telephone calls to Ilya Zborovsky at telephone no. (516)243-3818 and address all correspondence to:

Ilya Zborovsky
6 Schoolhouse Way
Dix Hills, N.Y. 11746

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: EPHSTEIN, Oleg Iliich

First inventor's signature: O. Ephstein Date: 3 Dec 1998

Residence & Post Office Address: 22 Yan Raiynis Blvd, D. 22, korp. Z, kv. 230, Moscow 123373 Russia

Citizenship: Russian

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